I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA

313-1450 on March 6, 2007

Attorney Docket No. CHM-021M

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Eric James WALL et al.

Confirmation No: 8880

Serial No.: 10/597,991

Filed:

8 5001

August 15, 2006

Title:

INJECTION DEVICE FOR ADMINISTERING A VACCINE

## INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§1.56, 1.97 and 1.98, Applicant request the Examiner to make of record the documents listed on the attached PTO/SB/08 form in connection with examination of the aboveidentified patent application. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b). In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due.

Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.P./

Receipt date: 03/08/2007 10597991 - GAU: 3763

Attorney Docket No. CHM-021M

This submission does not represent that a search has been made or that no closer art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Respectfully submitted,

Daniel F. Nesbitt Attorney for Applicant Registration No. 33,746

(513) 229-0383

Customer Number 38155

March 6, 2007

		Attorney Docket No. CHM-021M
	Con	nplete if Known
ı	Application Number	10/597,991
•	Filing Date	08/15/2006
	First Named Inventor	Eric James Wall
	Art Unit	
	Examiner Name	

CHM-021M

Attorney Docket Number

## INFORMATION DISCLOSURE MAR 08 SFATEMENT BY APPLICANT (use as many sheets as necessary)

1 of 5 Sheet

U.S. PATENT DOCUMENTS **Document Number** Pages, Columns, Lines, Where Cite **Publication Date** Name of Patentee or Examiner Relevant Passages or Relevant Number - Kind Code2 (if known) Initials\* MM-DD-YYYY Applicant of Cited Document No.1 Figures Appear US-2,671,488 03/09/1954 Harnisch US-12/04/1962 3,066,670 Stauffer US-3,572,336 03/23/1971 Hershberg US-3,605,742 09/20/1971 Tibbs US-3,702,608 11/14/1972 Tibbs US-4,031,889 06/28/1977 Pike US-4,043,333 08/23/1977 Munsch US-4,085,748 04/25/1978 Boyer US-4,194,505 03/25/1980 Schmitz US-4,196,732 04/08/1980 Wardlow US-4,214,584 07/29/1980 Smirnov et al. US-4,227,528 10/14/1980 Wardlow US-4,267,836 05/19/1981 Whitney et al. US-4,270,537 06/02/1981 Romaine US-04/27/1982 4,326,517 Whitney et al. US-4,340,048 07/20/1982 Eckenhoff US-4,373,526 02/15/1983 Kling US-4,512,767 04/23/1985 Denance US-11/12/1985 4,552,561 Eckenhoff et al. US-4,734,092 03/29/1988 Millerd US-4,753,651 06/28/1988 Eckenhoff US 4,846,808 07/11/1989 Haber et al. US-4,886,499 12/12/1989 Cirelli et al US-4,894,054 01/16/1990 Miskinyar 09/11/1990 US-4,955,871 **Thomas** US-4,968,302 11/06/1990 Schluter et al. US-5,019,047 05/28/1991 Kriesel 01/07/1992 US-5,078,680 Sarnoff US-5,137,516 08/11/1992 Rand et al. US-5,156,591 10/20/1992 Gross et al. US-5,167,632 12/01/1992 Eid et al. US-12/08/1992 5,169,389 Kriesel et al US-5,205,820 04/27/1993 Kriesel US-5,236,419 08/17/1993 Seney 12/07/1993 US-5,267,963 Bachynsky US-5,279,544 01/18/1994 Gross et al US-5,279,558 01/18/1994 Kriesel

Examiner	/Nathan Price/	Date	01/21/2009
Signature		Considered	0 (1111) 2000

				Complete if Known		
INF	ORMATION	N DIS	CLOSURE	Application Number	10/597,991	
	TEMENT B			Filing Date	08/15/2006	
		) I AI	ILICANI	First Named Inventor	Eric James Wall	
	(use as many she	ets as neces	sary)	Art Unit		
				Examiner Name		
Sheet	2	of	5	Attorney Docket Number	CHM-021M	

Examiner Initials*	Cite	Numb	Document Number  per - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
madis	10.	US-		.1		Figures Appear
		US-	5,318,557	06/07/1994	Gross	
			5,336,188	08/09/1994	Kriesel	
		US-	5,352,201	10/04/1994	Jemmott	
		US-	5,354,287	10/11/1994	Wacks	
		US-	5,419,771	05/30/1995	Kriesel	
		US-	5,478,315	12/26/1995	Brothers et al.	
		US-	5,527,288	06/18/1996	Gross et al.	
		US-	5,527,287	06/18/1996	Miskinyar	
		US-	5,578,014	11/26/1996	Erez et al.	<u> </u>
		US-	5,616,123	04/01/1997	Cheikh	
		US-	5,616,128	04/01/1997	Meyer	
		US-	5,616,132	04/01/1997	Newman	
		US-	5,656,032	08/12/1997	Kriesel et al.	
		US-	5,681,291	10/28/1997	Galli	
		US-	5,693,018	12/02/1997	Kriesel et al.	
		US-	5,695,463	12/09/1997	Cherif-Cheikh	
		US-	5,704,520	01/06/1998	Gross	
		US-	5,704,911	01/06/1998	Parsons	
		US-	5,735,818	04/07/1998	Kriesel et al.	
		US-	5,762,634	06/09/1998	Davis	
		US	5,769,826	06/23/1998	Johnson et al.	
		US-	5,785,688	07/28/1998	Joshi et al.	
		US-	5,791,466	08/11/1998	Tsals	
		US-	5,800,420	09/01/1998	Gross et al.	
		US-	5,807,375	09/15/1998	Gross et al.	
		US	5,810,775	09/22/1998	Shaw	
		US-	5,814,020	09/29/1998	Gross	<u> </u>
		US-	5,820,622	10/13/1998	Gross et al.	
		US-	5,848,991	12/15/1998	Gross et al.	
		US-	5,848,990	12/15/1998	Cirelli et al.	
		US-	5,858,001	01/12/1999	Tsals et al.	*****
		US-	D-404,366	01/19/1999	Gross et al.	
		US-	D-404,482	01/19/1999	Falk et al.	
		US-	D-405,524	02/09/1999	Falk et al.	
		US-	5,871,125	02/16/1999	Gross	
		US-	5,885,250	03/23/1999	Kriesel et al.	
$\overline{}$		US-	5,921,963	07/13/1999	Erez et al.	<del></del>

	Examiner Signature	/Nathan Price/	Date Considered	01/21/2009
--	-----------------------	----------------	--------------------	------------

				<del></del>	THIOTHEY BOOKET ING. CTHVI-02110	
ł				Complete if Known		
INF	ORMATION	v Dis	CLOSURE	Application Number	10/597,991	
i	TEMENT B			Filing Date	08/15/2006	
		) i Ai	LICANI	First Named Inventor	Eric James Wall	
	(use as many she	eets as neces	sary)	Art Unit		
				Examiner Name		
Sheet	3	of	5	Attorney Docket Number	CHM-021M	

			Document Number		Pages, Columns, Lines, Where		
Examiner Initials*	Cite No.1	l.	mber - Kind Code² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	
		US-	5,931,814	08/03/1999	Alex et al.		
		US-	5,957,895	09/28/1999	Sage et al.		
		US-	5,997,501	12/07/1999	Gross et al.		
-		US-	6,042,565	03/28/2000	Hirschman et al.		
		US-	6,048,334	04/11/2000	Hirschman et al.		
		US-	6,077,247	06/20/2000	Marshall et al.		
·		US-	6,086,562	07/11/2000	Jacobsen et al.		
-		US-	6,132,395	10/17/2000	Landau et al.		
		US-	6,146,361	11/14/2000	DiBiasi et al.		
		US	6,152,901	11/28/2000	Arruego et al		
		US-	6,157,858	12/05/2000	Gross et al.		
		US	6,162,197	12/19/2000	Mohammad		
		US-	6,186,982B1	02/13/2001	Gross et al.		
		US	6,254,575	07/03/2001	Thorne, Jr. et al.		
		US-	6,264,629 B1	07/24/2001	Landau		
		US-	2001/0012926 A1	08/09/2001	Gross et al.		
		US-	6,312,412	11/06/2001	Saied		
		US	2001/0039401	11/08/2001	Ferguson et al.		
		US-	6,319,224 B1	11/20/2001	Stout et al.		
		US	2002/0004648	01/10/2002	Larsen et al.		
		US-	6,364,865 B1	04/02/2002	Lavi et al.		
		US-	2002/0055711 A1	05/09/2002	Lavi et al.		
		US-	2002/0123719 A1	09/05/2002	Lavi et al.		
		US-	6,478,771	11/12/2002	Lavi et al.		
		US-	6,482,176B1	11/19/2002	Wich		
		US-	6,485,461B1	11/26/2002	Mason et al.		
		US-	6,494,865 B1	12/17/2002	Alchas		
		US-	6,500,150	12/31/2002	Gross et al.		
		US-	2003/0023203 A1	01/30/2003	Lavi et al.		
		US-	6,530,900	03/11/2003	Daily et al.		
		US-	6,530,904B1	03/11/2003	Edwards et al.		
		US-	6,569,123 B2	05/27/2003	Alchas et al.		
		US-	6,569,143 B2	05/27/2003	Alchas et al.		
		US-	2003/0100862A1	05/29/2003	Edwards et al.		
		US-	6,572,740	06/03/2003	Rosenblum et al.		
		US-	2003/0105430 A1	06/05/2003	Lavi et al.		
		US-	2003/0109827 A1	06/12/2003	Lavi et al.		

Examiner	/Nathan Price/	Date	01/21/2009
Signature		Considered	

					Timetral Description Office Office	
				Complete if Known		
INF	ORMATION	N DIS	CLOSURE	Application Number	10/597,991	
	TEMENT B	-		Filing Date	08/15/2006	
SIA		) I AF	FLICANI	First Named Inventor	Eric James Wall	
	(use as many she	ets as neces	sary)	Art Unit		
				Examiner Name		
Sheet	4	of	5	Attorney Docket Number	CHM-021M	

Eveminer	Cite	L	Document Number	Publication Date	News of Datastas as	Pages, Columns, Lines, Where
Examiner Initials*	No.1	Number - Kind Code² (if known)		MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		US-	6,585,707 B2	07/01/2003	Cabiri et al.	
		US-	6,589,210 B1	07/08/2003	Rolfe	
		US-	6,589,229B1	07/08/2003	Connelly et al.	
		US-	2003/0135159 A1	07/17/2003	Daily et al.	
		US-	6,595,947 B1	07/22/2003	Mikszta et al.	
		US-	6,595,956B1	07/22/2003	Gross et al.	
		US-	6,605,064B2	08/12/2003	Katch	
		US-	2003/0187395A1	10/02/2003	Gabel et al.	
		US-	6,645,180B1	11/11/2003	Hatch	
		US-	6,699,218B2	03/02/2004	Flaherty et al.	
		US-	6,702,779B2	03/09/2004	Connelly et al.	
		US-	6,749,587B2	06/15/2004	Flaherty	
		US	6,752,798	06/22/04	McWethy et al.	
		US	6,808,512	10/26/2004	Lin et al.	

		FOREIG	N PATENT	DOCUMENTS	
Examiner Initials*	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or
	No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Figures Appear 6
		WO 9317754 A1	09/16/1993	Elan Medical Technologies Ltd.	
		WO 9323096 A1	11/25/1993	Gross, Joseph	
		WO 9423777 A1	10/27/1994	Elan Medical Technologies Ltd.	
	EP 0651667 B1		05/10/1995	Elan Medical Technologies Ltd.	
		WO 9513838 A1	05/26/1995	Elan Medical Technologies Ltd.	
		WO 9532013 A1	11/30/1995	Elan Medical Technologies Ltd.	
		WO 9709078 A1	03/13/1997	Elan Medical Technologies Ltd.	
		WO 9710012 A1	03/20/1997	Elan Medical Technologies Ltd.	
		WO 9829662 A1	07/09/1998	Elan Medical Technologies Ltd.	
		WO 9959665 A1	11/25/1999	Elan Corporation, PLC	
		WO 0044437 A1	08/03/2000	Elan Pharma International Ltd.	
		WO 0202165 A2	01/10/2002	Elan Pharma Int'l Ltd.	

			- '- '- '- '- '- '- '- '- '- '- '- '- '-
Examiner	/Nathan Price/	Date	01/21/2009
Signature		Considered	01/21/2009

Receipt date: 03/08/2007 10597991 - GAU: 3763

				Complete if Known		
INFORMATION DISCLOSURE				Application Number	10/597,991	
STATEMENT BY APPLICANT				Filing Date	08/15/2006	
			ILICANI	First Named Inventor	Eric James Wall	
(use as many sheets as necessary)				Art Unit		
				Examiner Name		
Sheet	5	of	5	Attorney Docket Number	CHM-021M	

Examiner Initials*	Cite	* I magazino journal corial cumpocium agtalag etc.) data pagala) valuma iagua pumbarla) publichar aitu andlar I				
miliano	110.	country where published.				
		SCARFONE, Richard J., et al., Pain of Local Anesthetics: Rate of Administration and Buffering, Annals of Emergency Medicine, 01/1998, 31.1, 36-40				
		EDLISCH, Richard F., et al., Performance of Disposable Needle Syringe Systems for Local Anesthesia, The Journal of Emergency Medicine, Vol 5 pp. 83-90, 1987				
		KRAUSE, Richard S., The Effect of Injection Speed on the Pain of Lidocaine Infiltration, Academic Emergency Medicine, 11/1997, Vol 4/No 11, pgs. 1032-1035				
		MITCHELL, Jane R. et al., The Effect of Injection Speed on the Perception of Intramuscular Injection Pain, AAOHN Journal, 06/01, Vol. 49, NO. 6, pgs. 286-292	<del>-</del>			
		GRAVEN-NIELSEN, T., et al., In Vivo Model of Muscle Pain: Quantification of Intramuscular Chemical, Electrical, and Pressure Changes Associated with Saline-Induced Muscle Pain in Humans, Pain 69 (1997) pgs. 137-143				
		GRAVEN-NIELSEN, T., et al., Quantification of Local and Referred Muscle Pain in Humans after Sequential i.m. Injections of Hypertonic Saline, Pain 69 (1997) pgs. 111-117				
		CompuDent™, Milestone Scientific, 2002, www.milesci.com/cumpudent/index.php				
		When Patient Care Needs to Be Pain Free, PainFree pump, Sgarlato Labs, www.sgarlatolabs.com/pain_management.shtml, 2 pages; first publication date unknown				
		Uniject <sup>TM</sup> Injection System Overview, PATH, 8 pages, www.path.org/technos/uniject-overview.htm; first publication date unknown				
	,	Insulin Pump Technical Specifications, Debiotech S.A., Switzerland, www.debiotech.com/products/msys/ip_page_2.html; March 4, 2002, 1 page				
		MAILLEFER, Didier, et al., A High-Performance Silicon Micropump for Disposable Drug Delivery Systems, 0-7803-5998-4/01 IEEE, pgs. 413-417, 2001				
		The MEDIPAD System Benefits and Applications, Elan Medical Technologies, 990M001, 2002, RevJan2003, 2 pages				
		BD Medical brochure, Franklin Lakes, NJ, www.bd.com, 2003, 1 page				
		National Collegiate Inventors & Innovators Alliance (NCIIA), Advanced E-Team, Grant Profile, Painless Injection Method and Device, publication January 30, 2002, 1 page				
		Beckton, Dickinson and Company brochure, BD™ Disposable Pen, 2000, 2 pages				
	·	Beckton, Dickinson and Company brochure, BD™ Auto-Injector, 2000, 2 pages				

	<del></del>		
Examiner	/Nathan Price/	Date	01/21/2000
Signature		Considered	01/21/2009

COPENDING U.S. PATENT APPLICATIONS				
Examiner Initials*	Applicant(s)	Serial No.	Filing Date	Atty. Docket No.
	Wall et al.	10/605,187	09/12/2003	CHM-005M
	Wall et al.	10/597,997	08/15/2006	CHM-022M

	<del></del>		
Examiner	/Nathan Price/	Date	01/21/2009
Signature		Considered	0772172000